Please add the enclosed page 130 which contains an abstract of the disclosure as required under 37 C.F.R. Section 1.72(b). Entry of this abstract by the Examiner is respectfully requested.

REMARKS

Reconsideration of the above-identified application in view of the foregoing amendments and following arguments is respectfully requested.

Claims 29-34 have been deleted and new claims 35-40 have been added. No new matter has been added as a result of the addition of these new claims.

Priority Information

In the Office Action, the Examiner indicated that Applicant had not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. Section 120, because the first line of the specification had not been amended to indicate that priority was being claimed. Applicants thank the Examiner for pointing this out. Applicants have amended the specification to recite that the instant application claims priority under 35 U.S.C. Section 371 to PCT/EP98/08271 filed on December 16, 1997.

Documents Cited in the International Search Report

The Examiner indicated that the documents cited in the International Search Report had been considered. The Examiner invited the Applicants to provide an Information Disclosure Statement to make such documents of record in the instant application. Applicants thank the Examiner for pointing this out and enclose herewith an Information Disclosure Statement citing the documents in the International Search Report for inclusion in the record.

Abstract of the Disclosure

The Examiner indicated that the application did not contain an abstract of the disclosure as required by 37 C.F.R. Section 1.72(b). Applicants herewith enclose an abstract on a separate sheet. Applicants respectfully request entry of the abstract by the Examiner.

Title of the Invention

The Examiner indicated that the title of the invention was not descriptive. Applicants have amended the title of the invention so that it is clearly indicative of the invention to which the claims are directed.

Formal Drawings Under 37 C.F.R. Section 1.84

The drawings have been rejected for failing to comply with 37 C.F.R. Section 1.84 as outlined on the PTO-948 form attached to the Office Action. Applicants would like to hold the filing of new drawings in abeyance until receipt by the Examiner of allowable subject matter.

Rejection of Claims 29-31 Under 35 U.S.C. Section 101

Claims 29-31 are rejected under 35 U.S.C. Section 101 as essentially not being a proper process claim. Claims 29-31 have been deleted. Applicants have taken this rejection into consideration in drafting new claims 35-40. Thereupon, in view of the aforementioned amendments, Applicants submit that this rejection is now moot and should be withdrawn.

Rejection of Claims 29-32 Under 35 U.S.C. Section 112, Second Paragraph

Claims 29-32 are rejected under 35 U.S.C. Section 112, Second Paragraph, for a variety of reasons. First, with respect to claims 29-31, the Examiner stated that this claims were unclear because these claims did not set forth any steps involved in a method or process. Second, claims 29-31 were indefinite for depending, either directly or

indirectly, on a cancelled claim. Third, claims 29-34 were rejected as being incomplete for omitting essential steps.

Claims 29-34 have been deleted. Applicants have taken this rejection into consideration in drafting new claims 35-40. Thereupon, in view of the aforementioned amendments, Applicants submit that this rejection is now moot and should be withdrawn.

Rejection of Claims 32-34 Under 35 U.S.C. Section 102(b) as Anticipated by Kuroda et al.

Claims 32-34 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Kuroda et al. Claims 32-34 have been deleted. Applicants will now address this rejection with respect to new claims 35-40.

Anticipation requires that each and every element of the claimed invention be disclosed in the cited prior art reference.

Kuroda et al. disclose the results of a study that examined the mode of replication and temporal distribution of Creutzfeldt-Jakob disease (CJD)in relation to the onset of the disease. This article by Kuroda et al. was published in 1983, which was a time when it was still believed that the infective agent of CJD was a **virus** instead of an abnormal form of prions. This fact is recognized by Kuroda et al. who state that CRD is an "unconventional virus-induced slow infection of the central nervous system." Kuroda et al. simply do not disclose or suggest anything connecting prions with transmissible spongiform encephalopathy, let along the method of the present invention which involves identifying the presence of prions associated with transmissible spongiform encephalopathy in B and/or T-cells in a test sample. Thereupon, because each and every element of the claimed invention is not disclosed in Kuroda et al., Applicants submit that this rejection is not appropriate to new claims 35-40 and should be withdrawn.

Rejection of Claims 32-34 Under 35 U.S.C. Section 102(b) as Anticipated by Manuelidis et al.

Claims 32-34 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Manuelidis et al. Claims 32-34 have been deleted. Applicants will now address this rejection with respect to new claims 35-40.

Anticipation requires that each and every element of the claimed invention be disclosed in the cited prior art reference.

Manuelidis et al. teach that inoculation of the buffy coat of blood from guinea pigs infected with CJD resulted in passing this disease to the recipient animals. According to the authors, this finding demonstrates that there is a viremia in experimental CJD. The authors hypothesize that this hematogenous route might be implicated in human infection and that CJD might be transmitted by blood transfusions.

This article by Manuelidis et al. was published in 1978, which was a time when it was still believed that the infective agent of CJD was a **virus** instead of an abnormal form of prions. This fact is recognized by Kuroda et al. who state that the virus of CRD has been "found in the liver, kidney, lung, lymph nodes, and cerebral spinal fluid, and the virus of kuru has been found in lymph nodes, kidney, and spleen of humans." Manuelidis et al. simply do not disclose or suggest anything connecting prions with transmissible spongiform encephalopathy, let along the method of the present invention which involves identifying the presence of prions associated with transmissible spongiform encephalopathy in B and/or T-cells in a test sample. Thereupon, because each and every element of the claimed invention is not disclosed in Manuelidis et al., Applicants submit that this rejection is not appropriate to new claims 35-40 and should be withdrawn.

Rejection of Claims 29-34 Under 35 U.S.C. Section 103(a) as Obvious in view of O'Rourke et al., and/or Korth et al., in further view of Kuroda et al., and/or Manuelidis et al.

Claims 29-34 are rejected under 35 U.S.C. Section 103(a) as being obvious in view of O'Rourke et al., and/or Korth et al., in further view of Kuroda et al., and/or Manuelidis et al.

O'Rourke et al. disclose diagnostic assays for detecting PrP-Sc. The assay employs the third eyelid lymphoid tissue to detect PrP-Sc in ruminants (cattle, sheep, mule, deer, elk, etc.). The collected tissue sample is subjected to immunohistochemical or other protein-detecting methods to detect the presence of PrP-Sc. Also disclosed are monoclonal antibodies that bind to a conserved epitope on the ruminant PrP proteins in fixed or frozen tissue that has been treated to unmask the epitope to PrP-Sc and eliminate the availability to the corresponding epitope of PrP-C. These monoclonal antibodies bind to the conserved eptitope identified as Ile-His-Phe-Gly. As admitted by the Examiner, O'Rourke et al. fail to teach a method that involves the steps of collecting B cells and/or T cells from a test sample and then directly testing these cell types for the presence of prions associated with transmissible spongiform encephalopathy.

Korth et al. describe a monoclonal antibody, 15B3, which the authors claim can discriminate between the normal and disease-specific forms of PrP. According to the authors, this antibody should be "invaluable for characterizing the infectious particle as well as for diagnosis of TSEs such as bovine spongiform encephalopathy (BSE) or Creutzfeldt-Jakob disease (CJD) in humans." As with O'Rourke et al., the Examiner has admitted that Korth et al. fail to teach a method that involves the steps of collecting B cells and/or T cells from a test sample and then directly testing these cell types for the presence of prions associated with transmissible spongiform encephalopathy.

The deficiencies of O'Rourke et al. and/or Korth et al. are not cured by Kuroda et al. and/or Manuelidis et al. Collectively, these references teach that the infective agent of

transmissible spongiform encephalopathy was a virus. There is nothing in these references that would suggest to one skilled in art the causal connection between B-cells and T-cells and prions associated with transmissible spongiform encephalopathy. The inventors through their research were the first to discover the specific role of B-cells and T-cells with respect to TSE prions and to the practical applications resulting from this surprising finding.

Thereupon, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 01-0025.

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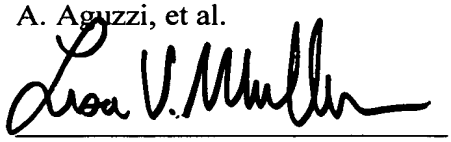

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